

## § 158.2150

## 40 CFR Ch. I (7–1–12 Edition)

these studies depending on the active ingredient being tested. Consultation with the Agency is advised before performing these Tier III studies.

### § 158.2150 Microbial pesticides nontarget organisms and environmental fate data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the terrestrial and aquatic nontarget organisms data requirements for a particular microbial pesticide product. Notes that apply to an individual test including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* Aquatic uses include: food and feed, nonfood uses (e.g., outdoor, residential, and industrial). Ter-

restrial uses include: Food, Feed, Non-Food, Forestry, Residential outdoor, greenhouse (food and food), Indoor (food and nonfood), and Industrial.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(d) *Table.* The following table shows the data requirements for microbial pesticides nontarget organisms and environmental fate. The test notes are shown in paragraph (e) of this section.

TABLE—MICROBIAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns								Test Substance	Test Notes
		Aquatic		Terrestrial							
				Food/ Feed/ Nonfood	For- est- ry	Res- i- den- tial	Green- house	Indoor	In- dus- trial		
						Out- door	Food/ Nonfood	Food/ Nonfood			
Tier I											
885.4050	Avian oral toxicity	R	R	R	R	R	CR	CR	CR	TGAI	1, 2
885.4100	Avian inhalation toxicity/pathogenicity	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	1, 2, 3
885.4150	Wild mammal toxicity/ pathogenicity	CR	CR	CR	CR	CR	NR	NR	CR	TGAI	1, 4
885.4200	Freshwater fish toxicity/ pathoge- nicity	R	R	R	R	CR	CR	CR	CR	TGAI or TEP	1, 2, 5
885.4240	Freshwater inverte- brate toxicity/patho- genicity	R	R	R	R	CR	CR	CR	CR	TGAI or TEP	1, 2, 5
885.4280	Estuarine/Marine fish testing Estuarine and marine invertebrate testing	CR	CR	CR	CR	CR	NR	NR	CR	TGAI	1, 6
885.4300	Nontarget plant testing	CR	CR	CR	R	CR	NR	CR	CR	TEP	1, 7
885.4340	Nontarget insect test- ing	R	R	R	R	R	CR	NR	CR	TGAI	1, 8
885.4380	Honey bee testing	R	R	R	R	R	CR	NR	CR	TGAI	1
Tier II											

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**TABLE—MICROBIAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA  
REQUIREMENTS—Continued**

Guideline Number	Data Requirement	Use Patterns								Test Substance	Test Notes
		Aquatic		Terrestrial							
				Food/ Feed/ Nonfood	For- est- ry	Res- i- den- tial	Green- house	Indoor	In- dus- trial		
						Out- door	Food/ Nonfood	Food/ Nonfood			
885.5200	Terrestrial environ- mental expression tests	CR	CR	CR	CR	CR	NR	NR	CR	TGAI or TEP	9
885.5300	Freshwater environ- mental expression tests	CR	CR	CR	CR	CR	NR	NR	CR	TGAI or TEP	10
885.5400	Marine or estuarine environmental ex- pression tests	CR	CR	CR	CR	CR	NR	NR	CR	TGAI or TEP	11, 12
Tier III											
885.4600	Avian chronic pathoge- nicity and reproduc- tion test	CR	CR	CR	CR	CR	NR	NR	CR	TGAI	12, 13
885.4650	Aquatic invertebrate range testing	CR	CR	CR	CR	CR	NR	NR	CR	TGAI	12, 14
885.4700	Fish life cycle studies	CR	CR	CR	CR	CR	NR	NR	CR	TGAI	12, 14
885.4750	Aquatic ecosystem test	CR	CR	CR	CR	CR	NR	NR	CR	TGAI	15
Tier IV											
850.2500 850.1950	Field testing for terres- trial wildlife and Field testing for aquatic organisms	CR	CR	CR	CR	CR	NR	NR	CR	TGAI or TEP	11, 16
850.2500	Simulated or actual field tests (birds, mammals)	CR	CR	CR	CR	CR	NR	NR	CR	TEP	16, 17, 20
850.1950	Simulated or actual field test (aquatic or- ganisms)	CR	CR	CR	CR	CR	NR	NR	CR	TEP	16, 18, 19, 20
850.2500	Simulated or actual field tests (insect predators, parasites)	CR	CR	CR	CR	CR	NR	NR	CR	TEP	16, 18, 19, 20
850.3040	Simulated or actual field tests (insect pollinators)	CR	CR	CR	CR	CR	NR	NR	CR	TEP	16, 18, 19, 20
850.4300	Simulated or actual field tests (plants)	CR	CR	CR	CR	CR	NR	NR	CR	TEP	16, 18, 19, 20

(e) *Test notes.* The following test notes are applicable to the data requirements for microbial pesticides nontarget organism and environmental fate as referenced in the last column of the table contained in paragraph (d) of this section.

1. Tests for pesticides intended solely for indoor application would be required on a case-by-case basis, depending on use pattern, production volume, and other pertinent factors.

2. The preferred species for the avian oral study is either the upland game or waterfowl. The preferred species for the avian inhalation toxicity/pathogenicity study and the avian chronic toxicity/pathogenicity study is the upland game. There is also the option to test the passerine if there is a concern. The coldwater fish is preferred for freshwater fish testing. However, two species (coldwater and warmwater fish species are the preferred species) must be tested for uses involving direct freshwater exposure. Freshwater invertebrate testing is also required.

3. Data required when the nature of the microbial pesticide and/or its toxins indicates potential pathogenicity to birds.

4. Required on a case-by-case basis if results of tests required by §158.2140 are inadequate or inappropriate for assessment of hazards to wild mammals.

5. Required when there will be significant exposure to aquatic organisms (fish and invertebrates).

6. Required if the product is intended for direct application into the estuarine or marine environment or expected to enter this environment in significant concentrations because of expected use or mobility pattern.

7. Required if the microbial pesticide is taxonomically related to a known plant pathogen.

8. Data are not required unless an active microbial ingredient controls the target insect pest by a mechanism of infectivity; *i.e.*, may create an epizootic condition in nontarget insects.

9. Required if toxic or pathogenic effects are observed in one or more of the following tests for microbial pesticides:

- i. Avian acute oral or avian inhalation studies.
- ii. Wild mammal studies.
- iii. Nontarget plant studies (terrestrial).
- iv. Honey bee studies.
- v. Nontarget insect studies.

10. Required when toxic or pathogenic effects are observed in any of the following Tier I tests for microbial pest control agents:

- i. Freshwater fish studies.
- ii. Freshwater invertebrate studies.
- iii. Nontarget plant studies (aquatic).

11. Required if product is applied on land or in fresh water or marine/estuarine environments and toxic or pathogenic effects are ob-

served in any of the following Tier I tests for microbial pesticides:

- i. Estuarine and marine animal toxicity and pathogenicity.
- ii. Plant studies - estuarine or marine species.

12. An appropriate dose-response toxicity test is required when toxic effects on nontarget terrestrial wildlife or aquatic organisms (including plants) are reported in one or more Tier I tests and results of Tier II tests indicate exposure of the microbial agent to the affected nontarget terrestrial wildlife or aquatic organisms. The protocols for these tests may have to be modified in accordance with results from the nontarget organism and environmental expression studies.

13. Required when one or more of the following are present:

i. Pathogenic effects are observed in Tier I avian studies.

ii. Tier II environmental expression testing indicate that long-term exposure of terrestrial animals is likely.

14. Required when product is intended for use in water or expected to be transported to water from the intended use site, and when pathogenicity or infectivity was observed in Tier I aquatic studies.

15. Required if, after an analysis of the microbial pesticide's ability to survive and multiply in the environment and what ecological habitat it would occupy, the intended use patterns, and the results of previous nontarget organisms and environmental expression tests, it is determined that use of the microbial agent may result in adverse effects on the nontarget organisms in aquatic environments. Testing is to determine if applications of the microbial pest control would be expected to disrupt the balance of populations in the target ecosystem.

16. Tier IV studies may be conducted as a condition of registration as post-registration monitoring if the potential for unreasonable adverse effects appears to be minimal during that period of use due to implementation of mitigation measures.

17. Required when both of the following conditions occur:

i. Pathogenic effects observed at actual or expected field residue exposure levels are reported in Tier III; and

ii. The Agency determines that quarantine methods would not prevent the microbial pesticide from contaminating areas adjacent to the test area.

18. Short term simulated or actual field studies are required when it is determined that the product is likely to cause adverse short-term or acute effects, based on consideration of available laboratory data, use patterns, and exposure rates.

19. Data from a long-term simulated field test (e.g., where reproduction and growth of confined populations are observed) and/or an actual field test (e.g., where reproduction

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and growth of natural populations are observed) are required if laboratory data indicate that adverse long-term, cumulative, or life-cycle effects may result from intended use.

20. Since test standards would be developed on a case-by-case basis, consultation with the Agency and development of a protocol is advised before performing these Tier IV studies.

### § 158.2160 Microbial pesticides product performance data requirements.

Product performance data must be developed for all microbial pesticides. However, the Agency has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control public health pests, such as pest microorganisms infectious to man in any area of the inanimate environment or a claim to control vertebrates (including but not limited to: rodents, birds, bats, canids, and skunks) or invertebrates (including but not limited to: mosquitoes and ticks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

### § 158.2170 Experimental use permit data requirements—microbial pesticides.

(a) *For all microbial pesticides.* (1) The following § 158.2171 through § 158.2174 identify the data requirements that are required to support experimental use permits for microbial pesticides. The variations in the test conditions are identified within the test notes.

(2) For general information on the data requirement tables, see § 158.2110(a)(2)-(4).

(b) *Additional data requirements for genetically modified microbial pesticides.* Additional requirements for genetically modified microbial pesticides may include but are not limited to: genetic engineering techniques used; the identity of the inserted or deleted gene segment (base sequence data or enzyme restriction map of the gene); information on the control region of the gene in question; a description of the “new” traits or characteristics that are intended to be expressed; tests to evaluate genetic stability and exchange; and selected Tier II environmental expression and toxicology tests.

### § 158.2171 Experimental use permit microbial pesticides product analysis data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the product analysis data requirements and the substance to be tested for a particular microbial pesticide. Specific conditions, qualifications, or exceptions to the designated test are identified in (d) of this section, and the test notes appear in paragraph (e) of this section.

(b) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; All=All of the above. Specific conditions, qualifications, or exceptions to the designated test procedures appear in paragraph (e) of this section, and apply to the individual tests in the following table:

(c) *Table.* The following table shows the data requirements for experimental use permit microbial pesticides product analysis. The test notes are shown in paragraph (d) of this section.

TABLE—EUP MICROBIAL PRODUCT ANALYSIS DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Pat-terns	Test Substance		Test Notes
			MP	EP	
Product Chemistry and Composition					
885.1100	Product Identity	R	MP	EP	--
885.1200	Manufacturing process	R	TGAI and MP	TGAI and EP	1, 2